UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION) CASE NO. 1:1 '	7-MD-2804
OPIATE LITIGATION)	
) HON. DAN AA	ARON POLSTER
THIS DOCUMENT RELATES TO:)	
)	
ALL CASES)	

PEC'S REPLY IN SUPPORT OF MOTION TO ENFORCE SUBPOENA FOR DEA PRODUCTION OF ARCOS TRANSACTIONAL DATA FOR 2015 TO 2019

The Plaintiffs' Executive Committee ("PEC"), on behalf of all MDL Plaintiffs, replies in further support of its Motion to Enforce Subpoena for DEA Production of ARCOS Transactional Data for 2015 to 2019 (Dkt. 5072-1) and in response to the Oppositions of the U.S. Drug Enforcement Administration ("DEA") (Dkt. 5072-2) and various Defendants.¹

ARGUMENT

I. The Updated ARCOS Data is Relevant to Ongoing MDL Cases.

The Court, DEA, and Defendants alike long have recognized that ARCOS transactional data is "relevant and necessary to litigation" of the Plaintiffs' claims in this MDL. Dkt. 233 (First ARCOS Order) at 7 and n.6 (citing arguments of counsel). As the Court explained when it first ordered nationwide production by DEA, "the ARCOS data is allowing both the litigation and settlement tracks of this MDL to proceed based on meaningful, objective data, not conjecture or speculation." Dkt. 397 (Second ARCOS Order) at 2. Indeed, the Court recently reaffirmed its recognition that the ARCOS data:

¹ The Defendants that filed Oppositions are Costco (Dkt. 5092), Settled Distributors (Dkt. 5093), Certain Non-Litigating Defendants (Dkt. 5094), Publix-Kroger (Dkt. 5095), and CVS, Walgreens, and Walmart ("Settled Pharmacies") (Dkt. 5096).

has proved "essential" in enabling the parties to file and amend complaints, design discovery, bring and defend motions, develop damages and abatement models, inform experts, prepare for trial, and engage in meaningful settlement discussions. The indispensable nature of this common fund of data, as produced to, organized in, and protected by this Court, vests it with a centrality to the nationwide opioids litigation unmatched in other MDLs.

Dkt. 5088 (Order to Establish Qualified Settlement Funds) at 18-19 (citation omitted); *see also* Dkt. 4428 (Ongoing Common Benefit Order) at 10 (same). DEA and Defendants thus do not and cannot dispute that ARCOS data is relevant to Plaintiffs' claims.

Instead, they argue that the 2006 to 2014 ARCOS data that the Court ordered produced has been enough for Plaintiffs to try or settle cases to date so that updated data is not necessary five years on.² This argument fails because the standard for obtaining discovery under Rule 26 is not whether the matter sought is "necessary," but whether it is "relevant" to a party's claim or defense. Fed. R. Civ. P. 26(b)(1); *see also Sweeney v. Nationwide Mut. Ins. Co.*, 2023 WL 2549549, at *3 (S.D. Ohio March 17, 2023) ("The Rule 56(d) inquiry—whether particular discovery is necessary before a party can properly respond to a motion for summary judgment—is narrower than the general relevance analysis under Rule 26(b)."). Since the Court found that ARCOS data through 2014 was "indispensable" to continuing public nuisance claims set for trial in 2019, updated ARCOS data detailing the prescription opioid supply through 2019 is relevant and increasingly important to current MDL cases for which trial will commence in or after 2024.

² DEA Opp. at 4 ("[T]he PEC has repeatedly established liability and market share with the ARCOS data in its possession."); Costco Opp. at 2 (Plaintiffs "already have access to nearly a decade of ARCOS data, and they have used it to successfully resolve dozens of cases"); Non-Litigating Defendants Opp. at 2 ("Plaintiffs can use the data they already have to advance any resolution with Remaining Defendants, just as they did with previous Defendants."); Settled Pharmacies Opp. at 2 ("The PEC did not seek or purport to need updated ARCOS data in the Track 3 trial, which concluded in May 2022. . . . The data was not needed in that case and similarly would not be needed in future cases.").

Several Defendants nonetheless try to freeze Plaintiffs' claims going forward to be based solely on the 2006 to 2014 prescription opioid supply without regard to how supply in intervening years bears on claims of a continuing public nuisance in and after 2024.³ These arguments cannot be squared with the Federal Rules of Evidence, under which "[e]vidence is relevant if it has any tendency to make a fact more or less probable than it would be without the evidence." Fed. R. Evid. 401. Here, if the 2015 to 2019 ARCOS data shows that the prescription opioid supply contracted while illicit opioid use was increasing, this would provide more support for Plaintiffs' theory that earlier-period prescription supply drove later-period illicit-use. Alternatively, if the 2015 to 2019 ARCOS data shows that the prescription supply held steady or increased and may have continued to fuel addiction, this too would bear on the non-settled Defendants' liability for the continuing nuisance based on their manufacturing, distribution, and/or dispensing conduct, particularly if these Defendants expanded their market presence during this period. In no event can Defendants and DEA force Plaintiffs to fly blind as to how the 2015 to 2019 prescription supply bears on their claims of a continuing public nuisance in and after 2024. The 2015 to 2019 prescription opioid supply is plainly relevant to Plaintiffs' claims.

Seeming to recognize this, the Settled Distributors argue for limiting production of updated ARCOS data to just that provided to DEA by non-settled Defendants.⁴ The Court should reject

³ Publix-Kroger Opp. at 2-3 ("The PEC has maintained . . . that the prescription-opioid wave ebbed by 2012, when the heroin wave took over. Because the originally-produced ARCOS data runs through 2014, it covers the so-called prescription-opioid wave in its entirety. . . . The 2015-2019 ARCOS data has no relevance to Plaintiffs' theories and would serve only to permit Plaintiffs to further complicate and expand what is already a complicated and expansive litigation."); Settling Pharmacies Opp. at 2 (same first two sentences).

⁴ Settled Distributors Opp. at 5 ("Settled Distributor Defendants have no active cases in the MDL at all."); *id.* at 7 ("[I]f the Court does order the production of additional ARCOS data it should expressly exclude data relating to the Settled Distributor Defendants."); *see also* Settled Pharmacies Opp. at 1 ("The parties and the Court should address discovery in a tailored fashion specific to the needs of the individual cases that remain.").

this argument. In its 2018 Orders, the Court directed DEA to produce "complete transactional ARCOS data . . . for the entire United States," Dkt. 397 at 2, without exception based on party or non-party status. The Court found that "all of the detailed information in the database is necessary" because identifying "precisely which manufacturers sent which drugs to which distributors, and which distributors sent which drugs to which pharmacies and doctors, is critical . . . to all of plaintiffs' claims[.]" Dkt. 233 at 7-8 (emphasis added). So it is here. Production of updated ARCOS data provided by Settled Distributors will enable Plaintiffs to determine, for example, how many of which drugs all distributors shipped to which non-settled Pharmacy Defendant, and what each non-settled Defendant's market share was in a Plaintiff's jurisdiction. As the Court has recognized since 2018, "complete" ARCOS data for the entire United States is relevant and important to Plaintiffs' claims.⁵

For the same reasons that complete ARCOS data is relevant to litigation of Plaintiffs' claims against non-settled Defendants, it also is relevant to potential settlement. Here, too, DEA and Defendants argue based on past cases that the ARCOS data the PEC already has is enough to guide settlement of all cases going forward.⁶ The PEC has shown how the 2015 to 2019 ARCOS

⁵ The Court also should reject the Settled Pharmacies' request to "limit the production of ARCOS data to the narrowed-scope of opioids agreed to in Track 3 known as the 'MDL 8' instead of the broader scope of opioids requested by the PEC, which is not limited to Schedule II opioids." Settled Pharmacies Opp. at 3. The Court in 2018 found all 14 of the opioid drugs the PEC addresses to be relevant. Third Order Regarding ARCOS Data (Dkt. 668) at 1 ("It has become clear, however, that there are a few gaps in the data necessary for the Court and the parties to obtain a complete picture *of the manufacture and distribution* of all opioid products at issue in this litigation.") (emphasis added). The Court should order the same production here.

⁶ DEA Opp. at 4 ("The PEC has already received nine years of ARCOS data, which was sufficient for Plaintiffs to . . . secure tens of billions of dollars in settlements against national opioid manufacturers, distributors, and retail pharmacies. Additional ARCOS data will not enhance the PEC's litigating posture or leverage in settlement negotiations."); Costco Opp. at 3 ("Given Plaintiffs' demonstrated ability to resolve cases using the existing ARCOS data, why do they suddenly claim to need more?"); Non-Litigating Defendants Opp. at 2 ("Plaintiffs can use the data they already have to advance any resolution efforts with Remaining Defendants, just as they did

data is relevant to litigation of Plaintiffs' current claims against unsettled Defendants. *See* Motion at 1-2; *supra* at 2-3. The fact that the PEC did not have the updated data when it resolved claims against other Defendants is of no moment. The PEC reached resolution with the Settled Manufacturers and Distributors after litigation that commenced in 2018, co-terminus with the Court's ARCOS Orders. The PEC reached resolution with the Settled Pharmacies after litigation that commenced in April 2020, within two years of the ARCOS Orders. *See* Dkt. 3282 (Order Regarding Track Three). Time has marched on. Plaintiffs' claims against Unsettled Defendants alleging a continuing public nuisance now are over five years removed from the ARCOS Orders and nearly ten years removed from the produced data. The relevance and increasing importance of the updated ARCOS data to litigation of Plaintiffs' claims establishes its relevance to settlement. Respectfully, it is not for Defendants or DEA to tell the PEC what relevant evidence it needs to evaluate MDL Plaintiffs' claims for settlement consistent with its fiduciary obligations.

The Court also should reject Defendants' argument that the updated ARCOS data would be disruptive to ongoing settlement negotiation.⁷ The PEC does not seek to stay any mediations, settlement negotiations, or Court Orders addressing the same. If the Court orders DEA to produce updated ARCOS data, the parties may continue mediating and negotiating before, during, and after DEA's production(s). To the extent that analyses of the updated ARCOS data bear on the parties'

with previous defendants."); Publix-Kroger Opp. at 2 ("The absence of ARCOS Data from 2015-2019 had no apparent effect on CVS', Walgreens', and Walmart's ability to settle claims on a national scope or the ability of plaintiffs nationwide to join those settlements."); Settled Pharmacies Opp. at 2 ("[T]he national settlements reached with CVS, Walgreens, Walmart and other major defendants were reached without such data.").

⁷ See Non-Litigating Defendants' Opp. at 2 ("[R]elease of updated ARCOS data will trigger costly efforts to review and interpret the data, including through retained experts."); *id.* at 3 ("Remaining Defendants would have to similarly engage consultants to review and interpret any new updated ARCOS data and any subsequent PEC analysis."); Publix-Kroger Opp. at 4 ("[T]he introduction of such data into these proceedings would cause unnecessary disputes and thus delay.").

negotiations, this only underscores the data's relevance to the claims at issue. Defendants' professed concern for or threat of disrupting settlement is not a ground for denying this discovery.

Finally, the Court also should reject Defendants' relevancy arguments addressed to amendment of Plaintiffs' Complaints. The PEC did not move on this basis, as Defendants know. Defendants do not and cannot identify authority for the proposition that discovery relevant to litigation of current claims may be disallowed based on its potential relevancy to *additional* claims. *Cf.* Fed. R. Civ. P. 26 advisory committee's note to 2015 Amendment ("Discovery that is relevant to the parties' claims or defenses may also support amendment to add a new claim or defense that affects the scope of discovery."). The Court should reject these arguments as grounds for denying discovery that is plainly relevant to Plaintiffs' existing claims.

II. Burden and Prejudice Concerns Do Not Warrant Denial of This Discovery.

DEA correctly argues that the Court struck a balance between relevancy and burden with its 2018 ARCOS Orders. As DEA notes, Opp. at 2, 10, the Court stated that "[t]his directive for release of additional ARCOS data will be the last one made *by the MDL Court*." Dkt. 668 at 2 (emphasis added). This reflected the Court's and the parties' reasonable expectation at that time—that the then-produced ARCOS data would guide litigation of bellwether cases and resolution

⁸ See Costco Opp. at 1 ("The Federal Rules make clear that the discovery process may not be used to hunt for new claims, and it is too late for Plaintiffs to amend their complaints in any event."); Non-Litigating Defendants' Opp. at 1 ("Second, Remaining Defendants object to the PEC's suggestion that they intend to use updated ARCOS data to pursue an expansion of the MDL by amending existing complaints or filing new lawsuits."); Publix-Kroger Opp. at 3 ("Such amendments would unnecessarily complicate and expand the MDL."); see also Settled Distributors' Opp. at 6 ("But even if the Court were to entertain a motion by the PEC to amend any particular complaint, the PEC certainly does not need more recent ARCOS data to do so visà-vis Settled Distributor Defendants.").

⁹ Costco Opp. at 1 (amendment is a rationale the PEC "did not include in its letter"); Settled Distributors' Opp. at 6 (amendment is "not asserted in the PEC's Letter Brief"); see also Non-Litigating Defendants' Opp. at 4 n.3 ("Remaining Defendants reserve all rights to object to any forthcoming motion for leave to amend").

before the MDL Court in the immediately-following years, so that discovery in any remaining cases would likely be within the purview of remand courts. What the Court and the parties *could not* have expected was that, after the resolution of Case Track 1, it would take six months to commence a viable bellwether case for pharmacy dispensing claims and then another 18 months of a pandemic before a jury could safely be seated for trial of that bellwether. As a result of these unforeseeable delays, five years passed from the 2018 ARCOS Orders to the resolution of most MDL claims against most Tier 1 Manufacturer, Distributor, and Pharmacy Defendants.

The passage of five years without resolution or bellwether development of cases against PBM and Tier 2 and 3 Defendants has made updated ARCOS discovery relevant and important to the MDL in 2023 in a way that the Court and the parties could not reasonably foresee in 2018. This is why the updated ARCOS data production the PEC seeks is consistent with the balance the Court sought to strike with its 2018 Orders by providing important fact information for MDL-wide litigation and settlement while also recognizing the burdens this production may place on DEA.

With respect to burden, DEA does not show that any of the burdens it alleges, Opp. at 4-5, is greater now than when it produced ARCOS data in 2018. The validation process that DEA says constitutes the "lion's share of the work," *id.* at 4, appears to be far *less* of a burden than it would have been for DEA in 2018. *Cf.* Dkt. 233 at 19 (ARCOS data "is validated by the DEA"). The PEC is requesting only five years of data (2015 to 2019), compared with the nine years of data (2006 to 2014) that DEA previously produced. Moreover, because the data is more recent, issues of legacy systems and conversion of older data are not present. Finally, when DEA made the prior production, the PEC itself performed substantial validation of the data. *See* Dkt. 3007-13 (CT1 Expert Report of Craig J. McCann, Ph.D., CFA) at 18-22 ("Exclusions and Corrections to ARCOS Data"); *compare id.* at 21 (Dr. McCann performed removal of "[t]ransactions where the Action

Indicator code, Correction Number, or both suggested the reported transaction is erroneous"), with DEA Opp. at 5 ("[T]he most burdensome process is validation, which requires DEA employees to cross reference any anomalies identified among millions of transactions."). The PEC stands ready to do the same or more here to help ensure that the updated ARCOS data likewise is properly validated while minimizing any burden on DEA. The PEC appreciates DEA's view of how the 2018 and 2023 productions together may impose a "cumulative burden," Opp. at 5, and commits to work cooperatively with DEA to streamline the production process while ensuring proper validation. DEA's burden arguments do not provide grounds for denying the PEC's Motion. ¹⁰

DEA also challenges the PEC's suggested production timeline as unduly burdensome. *Id.* at 6 ("The review process described above could not be completed for all the data requested within the timeline demanded by the PEC unless DEA devotes the full-time effort of at least five diversion employees (out of an office of sixteen) at the expense of all other required tasks."). The PEC suggested a timeline of 35 days based on the smaller five-year temporal scope of the production here than in 2018. In 2018, DEA produced nine years of national data in approximately three months. *See* Dkt. 397 at 2 (May 8 Order for production of first four drug types by May 25); Dkt. 668 at 2 (June 8 Order for rolling production of remaining ten drug types); Dkt. 3007-13 at 8 (McCann CT1 Report; productions completed by August 28). The 2018 production consisted of over 500,000,000 transaction records, each containing 34 information fields. Dkt. 3007-13 at 8 (transactions), 9-10 (information fields). The five years of data sought here will contain far fewer transactions, thus warranting a more compressed production timeline. The PEC, however, will

¹⁰ Indeed, the PEC has made several offers to USDOJ to reduce the potential burden on DEA, including by limiting the validation process or extending the time to perform it by producing preliminary, unvalidated data. While USDOJ has cooperated fully with the PEC, DEA has either rejected or not responded to these proposals.

work with DEA and the Court to identify an appropriate schedule, with possible staging by drug types, by data years, or otherwise. The production schedule likewise is not grounds for denying the PEC's Motion.

Nor do Defendants raise any argument on alleged burden or prejudice that provides grounds for denying the PEC's Motion. Defendants either parrot DEA's insufficient argument on burden¹¹ or assert that the production would burden them by disrupting ongoing settlement negotiation,¹² which it would not for the reasons set forth *supra* at 5-6. The Settled Distributors separately argue, as they did before, that any production of ARCOS data will cause them competitive harm and/or hamper their ostensible anti-diversion efforts.¹³ The Court previously rejected the arguments by Defendants and DEA alike that production of three-year-old ARCOS data would disrupt ongoing investigations and cause competitive harm to registrants. Dkt. 233 at 16 ("Given that the most recent data is over three years old, it is untenable that exposure of the data will actually or meaningfully interfere with any ongoing enforcement proceeding."); *id.* at 17 (rejecting competitive harm argument as "conclusory" and noting authority finding that "market data over three years old carried no risk of competitive harm"). The Court should rule the same here as to the Settled Distributors' renewed argument.

In sum, DEA and Defendants identify no burden or prejudice that would warrant denial of the PEC's Motion for production of updated ARCOS data through 2019 that is plainly relevant and important to Plaintiffs' claims of a continuing public nuisance in and after 2024.

¹¹ Settled Distributors' Opp. at 3-4; Non-Litigating Defendants' Opp. at 2.

Non-Litigating Defendants' Opp. at 2-3; Publix-Kroger Opp. at 4.

¹³ Settled Distributors' Opp. at 5-6 ("Without conceding that staleness is ever a sufficient basis for production, Settled Distributor Defendants specifically disagree that the 2015 to 2019 data is so old as to have lost either its competitive value or potential relevance to anti-diversion efforts.").

CONCLUSION

For all of the reasons set forth, the PEC's Motion to Enforce Subpoena for DEA Production of ARCOS Transactional Data for 2015 to 2019 should be granted.

Dated: July 7, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on July 7, 2023, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system. Counsel will serve a copy of the foregoing via email to F. Elias Boujaoude, US. Department of Justice, Civil Division, Fraud Section at F.E.Boujaoude@usdoj.gov.

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